NADA Number: 141-068	
Trade Name	Baytril® 100 Injectable Solution
Sponsor	Bayer Healthcare LLC, Animal Health Division
Ingredients	Enrofloxacin
Species	Cattle, dairy, females under 20 months of age Cattle, beef, excluding veal calves Swine, no use class stated or implied
Routes of Administration	Subcutaneous
Dose Form	Liquid (solution)
Drug Form	Liquid (solution)
Dispensing Status	RX
Patent Number	4670444 5756506
Exclusivity	Supplemental approval providing for the use of enrofloxacin in female dairy cattle less than 20 months of age. Supplemental approval provides for enrofloxacin use in the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, and Streptococcus suis in swine. This exclusivity is granted only for the newly approved species. Granted as the application contains additional evidence of the safety and effectiveness for the treatment of bovine respiratory disease (BRD) associated with Pasteurella haemolytica, P. multocida, and Haemophilus somnus.
Dosage Amount,	522.812 Enrofloxacin solution. Specifications. Each milliliter of sterile solution contains either 22.7 milligrams of enrofloxacin when intended for use in dogs or 100 milligrams of enrofloxacin when intended for use in cattle. Conditions of use: Cattle (beef and non-lactating dairy cattle) Amount: Single-dose therapy: 7.5 to 12.5 mg/kg of body weight (3.4 to 5.7 milliliters per 100 pounds) by subcutaneous injection. Multiple-day therapy: 2.5 to 5.0 mg/kg of body weight (1.1 to 2.3 milliliters per 100 pounds) by subcutaneous injection once daily for 3 to 5 days. Indications: For the treatment of bovine respiratory disease (BRD) associated with Mannheimia haemolytica, P. multocida, and Haemophilus somni (previously Haemophilus somnus).

Indications & Limitations	Limitations: Animals intended for human consumption must not be slaughtered within 28 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Use of enrofloxacin in this class of cattle may cause milk residues. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. Do not inject more than 20 milliliters at each site. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Swine Amount: Administer 7.5 mg/kg of body weight once, by subcutaneous injection behind the ear. Indications: For the treatment and control of swine respiratory disease (SRD) associated with Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, and Streptococcus suis. Limitations: Animals intended for human consumption must not be slaughtered within 5 days of receiving a single-injection dose.
Tolerances	A tolerance of 0.1 part per million for desethylene ciprofloxacin (marker residue) has been established in liver (target tissue) of cattle .